IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL LIABILITY EXPERTS

Plaintiffs devote their Opposition to Defendants' Motion to Exclude Plaintiffs' General Liability Experts ("Opposition") (Doc. 550) to attempting to validate Dr. David Bliesner's testimony regarding alleged Actavis quality systems deficiencies. They miss the point.

Plaintiffs make a last-gasp effort to reach "defect" by submitting Dr. Bliesner's eleventh hour declaration. There, for the first time in this litigation, Dr. Bliesner offers opinions that Actavis produced and released to market defective, out-of-specification Digitek®. These new opinions, submitted so late as to deprive Defendants of any ability to cross-examine Dr. Bliesner on them, are an improper supplement under Fed. R. Civ. P. 26(e)(2) and, further, are barred by the "sham affidavit" rule.

The key issue in this litigation is "defect." (*See McCornack* Doc. 116 at 6) ("Proving a manufacturing defect has been the key issue in this case, and every case in the MDL, since the beginning.") Plaintiffs defend Dr. Bliesner's credentials and methods for attacking Actavis's "quality systems," and by doing so focus entirely on a different issue—adulteration. Plaintiffs ignore the fact that testimony about deficient "quality systems" does not prove product "defect." Plaintiffs never respond to the argument that, as a matter of law and fact, an adulterated product is not *per se* defective and they simply presume otherwise.

Dr. Bliesner does not say "defect" or "out of specification" in his expert report, and Plaintiffs cannot bridge the analytical gap between adulteration and defect. (*See* Pls' Ex. 500). Dr. Bliesner (along with Plaintiffs' other experts) admits he has no evidence that any of the recalled Digitek® tablets in the market were defective—out-of-specification. In fact, he admits he is not capable of even ascertaining whether adulterated, much less out-of-specification, Digitek® tablets reached consumers.

Even if Dr. Bliesner could render such an opinion, he admits his opinions depend on a methodology that is less intellectually rigorous than he would otherwise use in his normal practice. Plaintiffs articulate no substantive response defending Dr. Bliesner's methodology for concluding defective Digitek® reached the market. Instead, from the "defective quality systems" conclusion, Plaintiffs and Dr. Bliesner make what Plaintiffs expressly acknowledge is an "inferential leap" to the conclusion that defective Digitek® (of unspecified quantity and/or character) "probably" reached the market.

Plaintiffs want to put Defendants on trial for general, non-Digitek®-specific regulatory issues and interaction with the FDA going back nearly 20 years, without proof that a single Digitek® tablet that was part of the recall reached the market. This is not what the tort system is for and Plaintiffs should be prohibited from making this type of attack.

I. DR. BLIESNER'S NEW AFFIDAVIT DELIBERATELY CHANGES AND MISCHARACTERIZES HIS PRIOR TESTIMONY TO FABRICATE DEFECT REFERENCES.

Plaintiffs proffer new testimony from Dr. Bliesner in the form of a newly executed affidavit submitted in support of their Opposition. (*See* Pls' Ex. 620). This new testimony should be disregarded for multiple reasons.

First, Dr. Bliesner's new affidavit is an obvious attempt to improperly supplement his prior opinions, openly tailored to be a response to Defendants' motions (1) to exclude his testimony and (2) for summary judgment. This violates Rule 26(e)(2). (*See* Doc. 570 at 7-8).

In addition, his affidavit is littered with testimony that contradicts his report and his prior deposition testimony and, as a result, violates the "sham affidavit" rule. (*Id.* at 8-10). For example, on page 43 of his expert report Dr. Bliesner discusses a UDL document that relates to testing conducted on Digitek® Batch 60319A. There, Dr. Bliesner properly comments that the UDL document indicates merely that the final blend assay standard deviation was "higher than other batches" although it was not out of specification. (Pls' Ex. 500 at 44, Bates 000705). Nevertheless, Dr. Bliesner now characterizes this circumstance as reflecting "blend uniformity *defects*, particularly with respect to Batch 60319A." (Pls' Ex. 620 at 4) (emphasis added).

On page 57 of his report Dr. Bliesner discusses assay testing conducted by Mylan on two batches of Digitek®, as reflected in Exhibit M-14. According to Exhibit M-14, the two batches "have low assay (96.2 and 97.3%)[.]" (Ex. M-14). The FDA-approved assay range for Digitek® is 90 to 105%. (*See* Pls' Ex. 16 at 46; Def. Ex. 32, 36). Both 96.2% and 97.3% are well within the approved specification; however, UDL has tighter assay specifications than Actavis. (*See* Ex. M-14; Ex. 1 attached hereto at 74-77). These assay values, therefore, are "low" only with respect to UDL's specifications. Dr. Bliesner correctly notes this in his report when he characterizes these results only as being "low" and does not say they are out-of-specification. (Pls' Ex. 500 at 58, Bates 000719). Now, however, when Plaintiffs are desperately trying to show he can reliably testify that defective product was released, Dr. Bliesner changes the characterization of these "low" assay values to "out of specification": "In January 2008, internal

e mail at Mylan (a Digitek® distributor), confirms two batches of Digitek® 0.125 mg tablets *with out of specification assays (too low)*." (Pls' Ex. 620 at 4) (emphasis added).

The significant contradictions in Dr. Bliesner's new affidavit demonstrate the dangers of allowing this new testimony to be submitted by Plaintiffs. Dr. Bliesner has prepared a lengthy expert report and was examined over two deposition sessions covering nearly 14 hours of testimony. Nowhere does Dr. Bliesner's report state that the two circumstances set forth above (or any of the additional similar circumstances discussed in Defendants' Reply in support of their Motion for Summary Judgment, Doc. 570) indicate *defective* Digitek® reached the market. Likewise, he did not identify any of those instances when he was explicitly asked during deposition what evidence he relied upon for his conclusion that adulterated or defective Digitek® reached the market. (Bliesner Dep. at 397:4-419:8). If he had stated those conclusions or opinions in his report or during deposition, Defendants would have examined him regarding the basis for those opinions. By offering them for the first time in response to Defendants' Motion to Exclude Dr. Bliesner, Defendants have no opportunity to evaluate the reliability of these opinions under *Daubert*. Dr. Bliesner's new opinions regarding defective and out-of-specification Digitek® should be barred for this reason alone, even if this Court does not find that either Rule 26(e)(2) or the "sham affidavit" rule exclude his declaration.

Moreover, these mischaracterizations are not a mistake. The available records clearly state the appropriate assay values. Dr. Bliesner is an analytical chemist by training and background. He is well versed in how to read production records and determine whether an assay value is out of specification. In fact, he explicitly acknowledged that a tablet which is not within the tighter UDL specifications, but is within the FDA-approved specifications, is not out-of-specification. (*Id.* at 523:3-524:14). He also knows whether a standard deviation value is

merely low or is actually out of specification. An individual with Dr. Bliesner's background, education, and training—an expert in cGMP compliance and assessment—does not inadvertently change a description of an assay value from low to out of specification, or inadvertently change a "higher than normal" reference to standard deviation to referring to it as a "defect." Dr. Bliesner's new testimony reflects knowing mischaracterization which runs contrary to the very essence of what he does and is trained to do, and must seen for what it is: a deliberate attempt to fabricate and create evidence of defect where none exists, in response to Defendants articulating substantial deficiencies in Dr. Bliesner's "defective product" analysis.

Dr. Bliesner knows he did not conduct a reliable analysis on the issue of product defect, so he has resorted to brazenly changing his testimony to suggest to the Court that there were actual instances of defective product in the market. His changes are a poorly disguised effort to try to support his opinion that Actavis did not have sufficient quality systems to prevent defective product from reaching the market and, therefore, that defective product must have reached the market. The starkness of Dr. Bliesner's attempts to knowingly mischaracterize evidence underscores the unreliability of Dr. Bliesner's analysis.[1]

[1] Dr. Bliesner and Plaintiffs also try to mislead the Court about defective Digitek® being released by including many references to events that have nothing to do with Digitek® or that he is not qualified to discuss. For example, Dr. Bliesner's list of "quality system failures" includes reference to a 1990 class II recall which supposedly related to "sub- and super-potent product." (Pls' Ex. 620 at 3). This recall occurred more than 20 years ago, and Dr. Bliesner conceded it was not a Digitek® recall 6 months before filing his affidavit. (Bliesner Dep. at 413). Including this event in his affidavit looks suspiciously like putting his "thumb on the scale." Likewise, Dr. Bliesner admits he is not a pharmacovigilance expert. (*Id.* at 208:4-11). For him to have multiple pharmacovigilance events as examples of quality system failures which support his deficient quality systems opinion is an open attempt to mislead the Court. (Pls' Ex. 620 at 3-5).

II. DR. BLIESNER IS NOT QUALIFIED TO GIVE OPINION TESTIMONY THAT DEFECTIVE DIGITEK® REACHED THE MARKET.

Defendants' Motion to Exclude sets forth a thorough explanation of why Dr. Bliesner is not qualified to render an opinion that defective Digitek® was released to market. (Doc. 526 at 18-19). This argument and evidence is unrefuted—Plaintiffs' Opposition makes no argument on whether Dr. Bliesner is qualified to offer opinion testimony *about whether defective Digitek® was released to market*. (Doc. 550 at 9-13). Defendants' Motion to Exclude Dr. Bliesner should be granted for this reason.

Instead, Plaintiffs leave the arguing on this issue to Dr. Bliesner in his proffered new "affidavit."[2] (Pls' Ex. 620 at 10-11). Dr. Bliesner mischaracterizes Defendants' argument, indicating Defendants claim he is "not an expert in the field of recalls." (*Id.* at 10). Defendants nowhere make any claim regarding Dr. Bliesner's status as an expert *with respect to recalls*; rather, Defendants clearly assert that Dr. Bliesner has acknowledged he is not capable of undertaking an analysis "of whether adulterated product reached consumers." (Doc. 526 at 18-19).

Dr. Bliesner also incorrectly asserts that Defendants' questions and his deposition testimony dealt with recalls. (Pls' ex. 620 at 10). Dr. Bliesner was never asked questions about the scope of the recall. He was asked very specifically how he would determine whether out-of-specification product reached the market—the first part of the analysis Dr. Bliesner now claims through his affidavit he is capable of making.

---

[2] The Court should disregard this testimony because Dr. Bliesner has crossed the line from witness to advocate. *See Hogan v. Novartis Pharms. Corp.*, No. 06 Civ. 0260(BMC)(RER), 2011 WL 1533467 at *4 (E.D.N.Y. April 24, 2011) (noting that expert witnesses were being improperly proffered to serve as scientifically informed advocates of conclusions the plaintiff wanted the jury to reach); *see also In re Air Crash Disaster at New Orleans, Louisiana*, 795 F.2d 1230, 1233 (5th Cir. 1986); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 283 (E.D.N.Y. 2007).

Q. Okay. Let's assume that a customer called you in for a consulting arrangement and they told you that they wanted to find out whether -- they had made some double thick tablets and they were interested in trying to figure out whether they had actually made it out of the plant to the distributor and all the way down to the customer level; okay?

A. Okay.

Q. Now, in order to figure that out --

A. Yes.

. . .

Q. The inquiry is we just don't know --

A. Right.

Q. -- And don't have the time to figure out whether --

A. Right.

Q. -- These actually got to consumers.

(Bliesner Dep. at 100:10-101:9).

This question was clear—Dr. Bliesner was asked how he would figure out whether double thick tablets which had been manufactured in a batch actually got to consumers. Dr. Bliesner understood the question; he answered without hesitation and indicated he would "source somebody in [his] consulting chain" to complete such analysis because "it's a different area altogether." (*Id.* at 101:11-17). Indeed, after Dr. Bliesner incorporated the concept of recall into his response, even though it was not in the question, he was asked another question which clearly removed the concept of recall:

Q. Okay. But the company that's consulting here isn't necessarily conducting a recall. They're just trying to figure out --

A. Whether --

Q. -- Whether it's a problem and maybe whether they should recall do you still farm that out? Sorry for the colloquialism. Do you still subcontract that to somebody else in your consulting chain?

A. Again if it's specifically looking at the impact, *is stuff out on the market*?

Q. Yeah.

A. Yeah, I would seek additional expertise.

(*Id.* at 102:2-14) (emphasis added).

The next exchange with Dr. Bliesner further confirms that he clearly understood he was not being asked about the scope of a recall:

> Q. So as part of your investigation in this case and your opinions in this case, in order to be consistent with your expertise, you would leave it to other experts to determine if out-of-specification Digitek® made it to the market, and if so, how much; is that right?
>
> A. If it made it to the market and how much. It wouldn't be binary -- you do it on or off if you will; okay? Hand it off. It would be something that I would be involved with from here are the data that suggests or show that adulterated product.
>
> Q. Was made?
>
> A. Was made.

(*Id.* at 102:24-103:12).

Contrary to what he now claims in his new declaration, Dr. Bliesner was not asked about "the nature and scope of a recall", or about whether he is an expert with respect to recalls, whether a recall should be undertaken, or, if so, the scope of the recall. (*See* Pls' Ex. 620 at 10). He was asked, directly, what he would do to assess whether defective product made it to the market. In response, he testified that he is not qualified to offer an opinion on that subject. Dr. Bliesner should be held to the standard created by his own testimony and he should not be permitted to testify about whether defective Digitek® was released to market.

III. PROVING ACTAVIS HAD DEFICIENT QUALITY SYSTEMS IS NOT SUFFICIENT TO SUPPORT EXPERT TESTIMONY THAT DEFECTIVE DIGITEK® WAS RELEASED TO MARKET.

Plaintiffs and Dr. Bliesner focus their *Daubert* argument entirely on whether Actavis had deficient quality systems. (Doc. 550 at 9-14; Pls Ex. 620 at 5-12). Even if Actavis had deficient quality systems, however, that fact does not prove anything with respect to whether defective Digitek® was released to market. At most, Dr. Bliesner's testimony that Actavis had defective or deficient quality systems proves only that some products manufactured by the deficient quality systems were, or had the potential to be, adulterated. (*See* Doc. 524 at 8-11). Plaintiffs are required to prove Digitek® was defective, not merely adulterated, or potentially defective or adulterated, and their proposition is flawed as a matter of law. (*Id.*). Any expert opinion that Actavis had deficient quality systems and that, therefore, defective Digitek® was released is inherently unreliable both factually and legally.

Under Plaintiffs' proposed approach, any plaintiff in America could file suit based on any FDA regulatory document for any pharmaceutical manufacturer that happens to manufacture a product taken by that plaintiff, regardless of whether the FDA document mentions the product that particular plaintiff actually takes. That plaintiff could allege product defect with respect to the product they take without doing any analysis of the attributes of their specific product—and even disregarding detailed manufacturing and production records which show their product was within specification—on the theory that the product (unmentioned in the FDA document) *must* have been defective because the company had regulatory issues which *could have* resulted in *their* product being defective. And Dr. Bliesner would be there to provide expert testimony that it *must have* been defective. The scope and potential impact of this proposition is stunning and it should be quickly rejected, as it has been by courts who have previously encountered it. *See, e.g., Myers-Armstrong v. Actavis Totowa LLC*, No. C 08-04741 WHA, 2009 WL 1082026, at *4

(N.D. Cal. Apr. 22, 2009), *aff'd* No. 09-16055, 2010 WL 2232652 (9th Cir. June 3, 2010); Doc. 524 at 10.

IV. THE METHOD DR. BLIESNER USED TO CONCLUDE ACTAVIS RELEASED DEFECTIVE DIGITEK® TO MARKET IS NOT RELIABLE.

Dr. Bliesner "leaps" from his opinion that Actavis had deficient quality systems to his opinion that Actavis released defective Digitek® to the market strictly by inference. (Doc. 550 at 13).[3] Dr. Bliesner has no "direct proof" that out of specification tablets reached consumers and has seen no report from any Plaintiff in this litigation reflecting a tablet outside its specifications in the market. (Bliesner Dep. at 88:14-90:11, 442:4-443:16). He reviewed only one batch record (Batch 70924) and does not know if any extra thick tablets from batch 70924 made it to consumers. (*Id.* at 447). The sole basis for Dr. Bliesner's testimony is the inferential leap from the regulatory record to a conclusion that defective tablets were both made and shipped. And the regulatory record – by and large – is unrelated to Digitek®.

Incredibly, Plaintiffs gloss over this remarkable reality by simply suggesting the inferential leap is "not long." (Doc. 550 at 13). *Daubert* requires a reliable method. An inferential leap—no matter how big—is not sufficient under the circumstances. And when several inferential leaps are stacked upon one another, each unsupported by law or fact, the deficiency in the methodology becomes even clearer.

Dr. Bliesner's newly submitted "affidavit" does not cure the obvious unreliability of the methodology he uses to conclude Actavis released defective Digitek® to the market. Dr. Bliesner (as well as Plaintiffs' other experts) testified about the appropriate method for

[3] In fact, Dr. Bliesner acknowledges that the only way he concludes that even *adulterated*—let alone defective—Digitek® made it to market is by inference, candidly acknowledging that the basis for this opinion is "The chronic systemic failure of the quality system and the FDA actions, including two consent decrees and anything like that, if you're defining that as an inference, then the answer would be yes." (Bliesner Dep. at 443:7-444:5).

determining whether adulterated and/or defective Digitek® was produced (let alone released to the market). The method Dr. Bliesner (and all of Plaintiffs' experts) testified was appropriate for conducting such an analysis is not the method Dr. Bliesner used to reach his product defect opinion here, and Dr. Bliesner's assertion that Defendants did not understand what he did and/or was purporting to do in this case is merely improper advocacy.[4]

Defendants did not ask the wrong questions of Dr. Bliesner. (*See* Doc. 550 at 10). Dr. Bliesner was asked during his deposition about how to perform an analysis and develop an opinion about whether a deficiency in a company's "quality system" related to or impacted a specific product.

> Q. …But Dr. Bliesner in that situation, if the FDA found a GMP deficiency in the quality systems and wanted then to inquire or determine whether that deficiency had any impact on a specific product --
>
> A. Yes.
>
> Q. -- What would they do?
>
> . . .

[4] Even Dr. Bliesner's irrelevant "deficient quality systems" opinion is based on a methodology much different than the one he would use if he was undertaking such an analysis as a consultant. Dr. Bliesner testified that, in the past when he has actually done them for clients, doing "very detailed assessments of the major quality system elements" requires that he and his team go "into individual departments -- laboratories, manufacturing areas, packaging areas -- usually in teams of two people and asking questions, performing interviews, looking at data, looking at protocols, the whole plethora of activities for each of the quality system elements. Document them… and you would go soup to nuts, systematic approach, looking through to see if they, in fact, had quality systems or any systems in place…and go back and write them up as findings from the assessment very similar to what the FDA would do on a 483. A very extensive, heavy duty process… You know, it was a detailed assessment and that would include reviewing training records for instance for the individuals that are there, looking at, you know, production records. Everything you would imagine that constitutes a modern pharmaceutical manufacturing system -- down to excruciating details." (Bliesner Dep. at 289:5-14; 290:1-10; 290:19-291:3). Dr. Bliesner obviously did not do that in this instance—he looked at virtually none of the production records he described as necessary to assess quality systems. Dr. Bliesner's opinion is nothing more than a restatement of information set forth on FDA regulatory documents. This does not qualify as proper expert testimony. *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337 (S.D. Florida 2010).

A. It depends, you know, what deficiency it is in quality systems; all right? For instance, let's say they go in the laboratory, they pull up some data, they look at chromatograms --

Q. Stop. Data and chromatograms for what? For the product?

A. Yes.

Q. Sounds to me like you're reviewing production records for that product.

A. They will review batch records as well.

Q. Okay.

A. Chromatographic data and reports aren't necessarily -- you know, they're included with the reported results, included in batch record, but the raw data and the stuff is not.

. . .

Q. But the bottom line is the FDA if they wanted to determine whether a quality systems deficiency impacted a specific product, they'd go look at the records, some portion of the records for that specific product, wouldn't they?

A. They'll look at the records that indicate where the difficulties are. For instance, if they think there's problems with an analytical method, they'll go in and they'll start pulling up chromatographic data, look at the results that come out there, look at peaks, look how they're innovated, pull up the development report, pull up the validation report things like that. If they think there are discrepancies with respect to improper documentation or execution of batch records, then they can pull the batch records and take a look at it.

Q. So what you've just described is a process whereby the FDA would look at some variation, some component -- some or all of the production records for the product. The only way they could conclude that a quality system deficiency actually impacted a specific product is to go look at the records that relate to that product; correct?

A. The raw data in the records, the reports that come out of it.

Q. Right.

A. That's correct.

(Bliesner Dep. at 452:22-455:16).

Plaintiffs claim Defendants seek to impose an "inapplicable standard[.]" (Doc. 550 at 10). But Defendants are merely applying the standard that all four of Plaintiffs' general liability experts (including Dr. Bliesner) expressly acknowledged is appropriate—reviewing Digitek®-specific records is essential and "critical" to properly evaluating whether Digitek® was adulterated and/or defective, regardless of whether there was a quality systems deficiency. (Doc. 526 at 9-23).

Reaching a conclusion about defect and distribution on nothing but an inference is not reliable, even for a quality system-wide issue. This is a manufacturing defect case. The production records are every bit as relevant and important—perhaps even more significant—to the issue of whether defective Digitek® was manufactured and/or released as are general cGMP compliance records which make no mention of defective Digitek® being released.

Dr. Bliesner had all of this information available to him—all batch records and thousands of pages of information and documents related to production of the recalled batches of Digitek® were produced to Plaintiffs and available to Dr. Bliesner. He chose to review none of it. (Bliesner Dep. at 86:2-87:5). He easily could have conducted the analysis he knows was proper; he did not, likely because Plaintiffs told him he would find nothing in the Digitek® production records, the FDA testing records, the Mylan/UDL testing records, or the Quantic records.

If Dr. Bliesner had reviewed the Digitek® production records he might be able to properly provide opinion testimony that defective Digitek® was released to market (even in the face of no defect being identified in the production records) because he would have, at least arguably, conducted a reliable analysis. Plaintiffs perhaps could then argue that the jury is entitled to hear Dr. Bliesner's testimony and give it appropriate weight, or discredit it, as they deem appropriate. But Dr. Bliesner must first conduct a reliable analysis. What he cannot do is disregard the

method he identified as proper and offer his opinions based on an "inferential leap." This is precisely the type of unreliable conjecture *Daubert* is intended to exclude.

V. THE TESTIMONY OF MR. FARLEY, MR. KENNY, AND DR. SOMMA SHOULD BE EXCLUDED.

Defendants have explained in careful detail why the proposed defective product testimony of Plaintiffs' other general liability experts (James Farley, Mark Kenny, and Russell Somma, Ph.D.) is unreliable. Each expert used a much less rigorous methodology here than they would use in the ordinary course of their respective professional practices. (Doc. 526 at 9-22). Plaintiffs make no effort to articulate specifically why the expert opinions of Mr. Farley, Mr. Kenny, and Dr. Somma are reliable and satisfy Daubert. (Doc. 550 at 13-14). Plaintiffs' entire "argument" regarding these three experts consists of stating that each "performed essentially the same analysis as Dr. Bliesner," followed by unsupported assertions that they all are qualified to offer opinions (1) about Actavis's quality systems and (2) that Actavis produced and released defective Digitek® to the market. (*Id.* at 13). Because Plaintiffs have not set forth any true argument on these issues, Defendants' Motion effectively stands unopposed with respect to Mr. Farley, Mr. Kenny, and Dr. Somma.

Moreover, assuming each expert performed the same analysis as Dr. Bliesner, then each expert formed his opinion that Actavis released defective Digitek® to market by using an "inferential leap" from some other conclusion. An inferential leap is no more reliable for these experts than it is for Dr. Bliesner's leap from "deficient quality systems" to defective product.

The proffered testimony of James Farley, Mark Kenny, and Russell Somma, Ph.D. that Actavis produced and released adulterated or defective Digitek® is not the result of a reliable analytical methodology. These three witnesses should be excluded.

CONCLUSION

Plaintiffs have put all of their general liability expert testimony needs on Dr. Bliesner's shoulders and make no effort to defend the opinions of Mr. Kenny, Dr. Somma, or Mr. Farley. To provide expert testimony that defective Digitek® reached the market, Dr. Bliesner is required to change and contort his prior testimony and knowingly mislead the Court. All of this flows from what is easily discerned from the record—Dr. Bliesner is not qualified to opine that defective Digitek® reached the market and did not use a reliable method to develop his opinion that it did. The opinions of Dr. Bliesner, Mr. Kenny, Dr. Somma, and Mr. Farley do not satisfy *Daubert* and they should be excluded.

GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL
500 Lee Street East, Suite 800
Charleston, West Virginia 25301
Tel: (304) 345-7250
Fax: (304) 345-9941
E-mail: rabetts@agmtlaw.com

Attorney for Defendants

SHOOK, HARDY & BACON LLP

Harvey L. Kaplan, CO-LEAD COUNSEL
Madeleine M. McDonough, CO-LEAD COUNSEL
2555 Grand Blvd.
Kansas City, Missouri 64108-2613
Tel: (816) 559-2214
Fax: (816) 421-5547
E-mail: hkaplan@shb.com
E-mail: mmcdonough@shb.com

Attorneys for Mylan, Inc. Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc., and UDL Laboratories, Inc.

TUCKER ELLIS & WEST LLP

/s/ Richard A. Dean
Richard A. Dean (Ohio Bar #0013165), CO-LEAD COUNSEL
Matthew P. Moriarty (WV Bar # 4571; Ohio Bar 0028389), CO-LEAD COUNSEL
925 Euclid Avenue, Suite 1150
Cleveland, Ohio 44115-1414
Tel: (216) 592-5000
Fax: (216) 592-5009
E-mail: richard.dean@tuckerellis.com
matthew.moriarty@tuckerellis.com

Attorneys for Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC

CERTIFICATE OF SERVICE

I hereby certify that on September 7, 2011, a copy of the foregoing **REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL LIABILITY EXPERTS** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL
500 Lee Street East, Suite 800
Charleston, West Virginia 25301
Tel: (304) 345-7250
Fax: (304) 345-9941
E-mail: rabetts@agmtlaw.com

Attorney for Defendants

SHOOK, HARDY & BACON LLP

Harvey L. Kaplan, CO-LEAD COUNSEL
Madeleine M. McDonough, CO-LEAD COUNSEL
2555 Grand Blvd.
Kansas City, Missouri 64108-2613
Tel: (816) 559-2214
Fax: (816) 421-5547
E-mail: hkaplan@shb.com
E-mail: mmcdonough@shb.com

Attorneys for Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc., and UDL Laboratories, Inc.

TUCKER ELLIS & WEST LLP

By: */s/ Richard A. Dean*
Richard A. Dean (Ohio Bar #0013165), CO-LEAD COUNSEL
Matthew P. Moriarty (WV Bar # 4571; Ohio Bar 0028389), CO-LEAD COUNSEL
925 Euclid Avenue, Suite 1150
Cleveland, Ohio 44115-1414
Tel: (216) 592-5000
Fax: (216) 592-5009
E-mail:richard.dean@tuckerellis.com
matthew.moriarty@tuckerellis.com

Attorneys for Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC